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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,493	06/08/2007	Takahide Kohro	032218A	1082

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EXAMINER	
PAGONAKIS, ANNA	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
12/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,493	KOHRO ET AL.	
	Examiner	Art Unit	
	ANNA PAGONAKIS	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-15 are currently pending in this application and are the subject of the Office action.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

It is noted that the "use claims" (i.e. 4, 5, 6, and 11) have been considered as a separate group because it is unclear whether these claims are directed to a method of using or method of making.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-3, drawn to a nuclear transfer promoter for Rac protein comprising an isoprenoid synthesis inhibitor and/or a geranylgeranyl transferase inhibitor. If this Group is elected, then the below Summarized Species Election is also required.

II. Claims 7-9, drawn to a method of promoting the transfer of Rac protein into a nucleus, which comprises administering an isoprenoid synthesis inhibitor and/or a geranylgeranyl transferase inhibitor to a cell. If this Group is elected, then the below Summarized Species Election is also required.

III. Claim 10, a pharmaceutical composition for vascular treatment. If this Group is elected, then the below Summarized Species Election is also required.

IV. Claim 12, drawn to a therapeutic/prevention method for vascular disorders comprising administering the nuclear transfer promoter for Rac protein in an effective amount for therapy/prevention to a patient in need of therapy/prevention

of vascular disorders. If this Group is elected, then the below Summarized Species Election is also required.

V. Claim 13-15, drawn to a method of screening a blood vessel remedy.

VI. Claims 4, 5, 6, and 11, alternatively drawn to the method of promoting nuclear transfer for Rac protein of an isoprenoid synthesis inhibitor and/or a geranylgeranyl transferase inhibitor.

VII. Claims 4, 5, 6 and 11, alternatively drawn to a nuclear transfer promoter for Rac protein comprising an isoprenoid synthesis inhibitor and/or a geranylgeranyl transferase inhibitor.

VIII. Claims 4, 5, 6 and 11, alternatively drawn to a process of making a nuclear transfer promoter for Rac protein comprising an isoprenoid synthesis inhibitor and/or a geranygeranyl transferase inhibitor.

Note: Claims 1-15 are improper claims encompassing the use of a nuclear transfer protein for Rac protein or multiple statutory classes of invention or undefined "uses". Amendment is required to correct their form. These claims can be interpreted as a method of treatment, a composition or process for making a composition. Therefore, they have been placed in Groups I-VIII for the purpose of this restriction requirement.

The inventions represented above as Groups I-VIII relate to a general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they share the same or corresponding technical features. Specifically, the technical feature of Groups I-VIII is the nuclear transfer promoter for Cdc42 protein. The inventions lack unity, however, as the common technical feature is known in the art as evidenced by the teaching of Kohro et al. (WO 2005/079847 A1; abstract only) of a nuclear transfer promoter for cdc42 protein comprising an isoprenoid synthesis inhibitor and/or a geranylgeranyl transferase inhibitor (see

abstract), and also Morikawa et al. (Morikawa et al. The effects of statins on mRNA levels of genes related to inflammation, coagulation, and vascular constriction in HUVEC, human umbilical vein endothelial cells. J. Atheroscler. Thromb. 2002; 9(4): 178-183; already made of record by applicant). Thus, the requirement is proper as the inventions represented above as Groups I-II lack unity of invention under PCT Rule 13.1.

Species Election regarding Groups I-VIII

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. For example, the generic inventions encompass a multiplicity of chemically distinct isoprenoid synthesis inhibitors, geranylgeranyl transferase inhibitors, and various different combinations of a isoprenoid synthesis inhibitor and a geranylgeranyl transferase inhibitor, which would reasonably exhibit different/variable pharmacologic, pharmaceutical, therapeutic, side effects profiles. The therapeutic effects to be achieved with these different compounds or combination species would reasonably differ substantially depending on the specific compound, as well as the doses and duration of treatment, and the contemplated targeted vascular disorder intended. Each vascular disorder represents a different distinct clinical entity. Therapeutic modalities used to treat a certain vascular disorder may not be effective to treat other types of vascular disease. Thus, these species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single species for purposes of examination from the below list:

1a) a single chemically defined isoprenoid synthesis inhibitor e.g. pitavastatin; or

1b) a single chemically defined geranylgeranyl transferase inhibitor; or

1c) a single combination of a compound from above item "1a" and a compound from above item "1b."

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to the additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after election, applicant must indicate which are readable upon the elected species (MPEP 809.02(a). Claims 1, 4, 5, 7, 10, 11, 12, and 13 are considered generic to the above species.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process

claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Inventorship Notice

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP

/Patricia A. Duffy/

Primary Examiner, Art Unit 1645